

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 34-R-0031
CUSTOMER NUMBER: 696

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

M P I Research Inc
54943 N. Main Street
Mattawan, MI 49071

Telephone: (269) -668-3336

NOV 09 2005

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report | F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E) |
|--|---|---|--|--|--|
| 4. Dogs | 593 | 2,882 | 721 | 0 | 3,603 |
| 5. Cats | 10 | 76 | 36 | 0 | 112 |
| 6. Guinea Pigs | 112 | 0 | 0 | 0 | 0 |
| 7. Hamsters | 1 | 25 | 0 | 0 | 25 |
| 8. Rabbits | 316 | 1,634 | 662 | 0 | 2,296 |
| 9. Non-human Primates | 206 | 1,978 | 197 | 4 | 2,179 |
| 10. Sheep | 4 | 1 | 32 | 0 | 33 |
| 11. Pigs | 142 | 360 | 525 | 0 | 885 |
| 12. Other Farm Animals | 0 | 0 | 0 | 0 | 0 |
| 13. Other Animals | | | | | |
| Chinchillas | 31 | 24 | 195 | 0 | 219 |

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

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Column E Explanation

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STUDY

- Number of Animals: 4
- Species : Monkey

- Explanation of Procedure Producing Pain and/or Distress

Monkey model of dermal treatment induced thermal allodynia. Allodynia is a phenomenon where a normally non-painful stimulus becomes painful. Allodynia is a common symptom in people that have suffered nerve damage, e.g., crush injuries or diabetic neuropathy. The goal of the study was to produce an area of enhanced sensitivity to normally non-noxious stimuli, to assess the anti-allodynic actions of test article. The animals were trained and acclimated to the test procedure, and were closely monitored by the technical staff and study director. The use of drugs to relieve the discomfort would have adversely affected the results and interpretation of the study.

- Scientific Justification

To assess the ability of the test articles to attenuate this allodynic response compared to control article response (baseline). The allodynic baseline was used to assess the potential anti-allodynic effects of test article. Administration of analgesics would have affected the assessment of the compounds being tested and given a false positive, or suppressed the model completely.

- Regulations

Direct communication between the Study Director and Sponsor representative. This study may be submitted to the U.S. Food and Drug Administration, and/or the Organization for Economic Cooperation and Development and/or the Japanese Ministry of Health, Labor and Welfare. The protocol for this test model was reviewed and approved by the Institutional Animal Care and Use Committee.

Summary of Exceptions

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Summary of Exceptions to the Regulations and Standards

- There were no exceptions to the regulations and standards.